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Food Safety Law Implementation Regulation

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Report Highlights:

On February 28, China's National People's Congress (NPC) Standing Committee passed the first comprehensive Food Safety Law (FSL) after five years of drafting. The FSL will go into effect on June 1, 2009. On April 24, the State Council published the first implementation regulation related to the new law. This report is an UNOFFICIAL translation of this regulation.

Includes PSD Changes: No
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Executive Summary: On February 28, China's National People's Congress (NPC) Standing Committee passed the first comprehensive Food Safety Law (FSL) after five years of drafting; the first draft was read in December 2007. The FSL will go into effect on June 1, 2009. On April 24, the State Council published the first set of implementation regulations related to the new law. The Legislative Affairs Office of the State Council (SCALO) is seeking public comments on this regulation by May 4, 2009. The original draft in Chinese can be found at http://news.xinhuanet.com/legal/2009-04/23/content_11243343.htm

According to Chinese Government contacts, this implementation regulation will be followed by regulations by the Administration for Quality Supervision, Inspection, and Quarantine (AQSIQ), State Administration of Industry and Commerce (SAIC), and the Certification and Accreditation Administration (CNCA) of China.

Neither the Food Safety Law (CH9019), nor this regulation has been notified to the World Trade Organization.

This report is an UNOFFICIAL translation of this implementing regulation.

BEGIN TRANSLATION

Regulations on the Implementation of Food Safety Law of the People's Republic of China (Draft)

Chapter I. General

Article 1. These regulations are formulated for the purpose of implementing the Food Safety Law of the People's Republic of China (hereinafter referred to as the Food Safety Law).

Article 2. Local people's governments at or above the county level shall reinforce their food safety supervision and administration capability building, so as to provide assurance to food safety supervision and administration work. The coordination and cooperation mechanism of food safety supervision and administration departments shall be established and perfected, food safety information network shall be integrated and perfected so that the access to technical information of food safety information institutions and food inspection institutions can be shared.

Article 3. Institutions under the State Council, such as the Ministry of Industry and Information Technology and the Ministry of Commerce, shall prepare the development program and industrial policies for food sector, promote industrial structure optimization and upgrading, guide trust building in food sector, and encourage its healthy development.

Chapter II. Food Safety Risk Monitoring, Assessment, and Food Safety Standard

Article 4. National food safety risk monitoring program, as provided for in Article 11 of Food Safety Law, shall be jointly developed according to the requirements of food safety risk assessment, food safety standard preparation or revision, and Administration for Quality Supervision, Inspection, and Quarantine (AQSIQ), State Administration for Industry and Commerce (SAIC), State Food and Drug Administration (SFDA) of the State Council, and the Ministry of Commerce (MOFCOM).

Article 5. The health administrative department of the people's government of each province, autonomous region, and municipalities directly under the Central Government shall organize its local AQSIQ, SAIC, food and drug administrative department, and commerce department to, pursuant to Article 11 of Food Safety Law, develop the food safety risk monitoring program for the local jurisdiction area and shall submit it to MOH for filing.

AQSIQ, SAIC, SFDA, and MOFCOM shall be briefed on this filing by MOH.

Article 6. The Ministry of Agriculture (MOA), AQSIQ, SAIC, SFDA, and MOFCOM shall collect food safety risk information and, when necessary the Ministry of Health (MOH), shall jointly adjust the food safety risk monitoring program in a timely manner.

Article 7. Apart from making adjustments to the food safety risk monitoring program in accordance with Article 12 of Food Safety Law, MOH shall, when necessary, adjust this program depending on the disease information as reported by medical institutions.

Article 8. A medical institution, when having received patients for food-borne disease and food poisoning, or suspected cases, shall report the disease information timely to the health administrative department of the county or district people's government.

After receiving the report, the local health administrative department shall summarize and analyze the disease information and shall, in a timely manner, report to its superior health administrative department and, if need be, it may report directly to MOH. Disease reporting regulations shall be prepared by MOH.

Article 9. Food safety risk monitoring work shall be undertaken by a technical institution as chosen jointly by MOH, SAIC, and SFDA.

The technical institution charged with food safety risk monitoring shall, in accordance with the food safety risk monitoring program, perform monitoring in a systematic and constant way, ensure that the monitoring data are true, accurate, and objective, and shall submit the monitoring data and analysis results to MOH and the department assigned the monitoring tasks.

In order to collect samples and relevant data, food safety risk monitoring personnel may enter the premises where farm food products are grown or developed or where food is processed, circulated or catering service provided; the samples shall be paid for.

Article 10. MOH shall collect and summarize food safety risk monitoring data and analyze the results and shall notify AQSIQ, SAIC, and SFDA, and MOFCOM.

Article 11. MOH shall arrange for food safety risk assessment in case of any one of the following circumstances:

(1) Where risk assessment is needed in order to provide scientific references to the development or revision of national food safety standard;

(2) Where risk assessment is needed in order to identify the key fields and key species of supervision administration and to assess the effectiveness of supervision administration measures;

(3) Where new factors are identified that may jeopardize food safety;

- (4) Where it is needed to determine whether a certain factor poses a food safety danger;
- (5) Where it is needed to determine whether a food is safe or not;
- (6) Where risk assessment is required pursuant Article 44 and 63 of Food Safety Law;
and
- (7) Other situations where MOH deems necessary to conduct a risk assessment.

Article 12. MOH shall notify MOA in a timely manner of food safety risk monitoring and risk assessment results.

MOA shall notify MOH in a timely manner of the quality and safety risk monitoring and risk assessment results of farm food products.

Where MOH, as may be needed for the purpose of food safety risk assessment, requires that MOA furnish safety assessment reports on pesticides, fertilizers, plant growth regulators, animal medicines, fodders, and fodder additives, MOA shall provide such information in a timely fashion.

Article 13. MOH shall, jointly with MOA, AQSIQ, SAIC, SFDA and MOFCOM, prepare a program and implementation plan for national food safety standard. Public comments and suggestions shall be invited for the preparation of the program and implementation plan for national food safety standard.

Article 14. MOH shall select technically qualified institutions to develop the draft of national food safety standard; it is recommended that the draft of the national food safety standard be developed jointly by research institutions, educational institutions, academic institutions, trade societies.

MOH shall publicize the draft of national food safety standard to society for comments and suggestions.

Article 15. The National Food Safety Standard Review Committee under Article 23 of Food Safety Law shall consist of experts selected by MOH and representatives MOA, AQSIQ, SAIC, and SFDA as well as representatives from the Ministry of Industry and Information Technology and MOFCOM.

The National Food Safety Standard Review Committee is responsible for reviewing the appropriateness and practicability of the draft of national food safety standard and its coherence with relevant national standards. The work procedures of the National Food Safety Standard Review Committee shall be prepared by MOH.

Article 16. The health administrative department of the people's government of each province, autonomous region, and municipality directly under the Central Government shall report on enterprise standards, as may be submitted for filing by local enterprises pursuant to Article 25 of Food Safety Law, to its local peer AQSIQ, SAIC, and SFDA.

Article 17. MOH shall, jointly with the agriculture administrative department, AQSIQ, SAIC, and state food and drug supervision department of the State Council as well as the Ministry of Commerce, follow up and assess the implementation of national food safety standard and shall, according to the assessment findings, arrange for a timely revision of this standard.

MOA, AQSIQ, SAIC, and SFDA shall, upon identifying any problems with the implementation of the food safety standard, notify MOH without delay.

Chapter III. Food Production and Business Operation

Article 18. Food producers or business operators shall, prior to applying for SAIC registration, have obtained a license for food production, food circulation, and catering services.

The food production license, food circulation license and catering service license are valid for 4 years.

Article 19. Should the production or operating conditions of a food producer or business operator have changed and, as a result, the requirements for food production and business operation are no longer satisfied, the food producer or business operator shall immediately stop production or operation activities and shall report to AQSIQ, SAIC, or SFDA of its local county or district.

Article 20. An enterprise engaging in food production or food business shall, as required by Article 32 of Food Safety Law, arrange for its employees to be trained in food safety, to study food safety laws, regulations, standards, and food safety knowledge, to understand food safety accountability, and maintain a training record.

Article 21. A food producer or food business operator shall, in accordance with Article 34 of Food Safety Law, establish and implement a health check system and health record system for food professionals. Food professionals engaging in work having direct contact with ready-to-eat food shall be relocated to other posts that will not have an influence upon food safety if they are suffering from a disease which, according to Food Safety Law, disqualifies them from engaging in such work.

Article 22. A food production enterprise shall establish and implement such food safety management systems as raw material acceptance management system, in-production safety management system, storage management system, equipment management system, unacceptable products management, and shall perfect food safety assurance systems so as to ensure food safety.

Article 23. A food production enterprise shall establish and implement control measures for key production processes like procurement and material charging, as well as control measures for packaging, storage, shipment, and inspection.

Whenever an occurrence not in compliance with the control measures is identified during food production, the food production enterprise shall immediately identify the cause and take corrective actions.

Article 24. Apart from maintaining a purchase acceptance inspection record and an ex-factory inspection record as required by Article 36 and 37 of Food Safety Law, a food production enterprise shall also record faithfully the safety management situation during food production. The records shall be kept for a minimum of 2 years.

Article 25. A food production enterprise performing an ex-factory food inspection pursuant to Article 38 of Food Safety Law shall retain the samples in a manner as required by relevant inspection regulations.

Article 26. A food operation enterprise practicing purchase acceptance inspection pursuant to Article 39 of Food Safety Law shall faithfully record such information as the name, specification, quantity, batch No., shelf life, name and means of contact of the supplier, and

purchase date of the food or alternatively keep the purchase bills that bear the above information. The records or bills shall be kept for a minimum of 2 years.

An enterprise engaging in food wholesale business shall, for the food sold, faithfully record such information as name, specification, quantity, batch No., shelf life, name and means of contact of the supplier, and sale date of the food or alternatively keep the sale bills that bear the above information. The records or bills shall be kept for a minimum of 2 years.

Article 27. The State encourages food producers and food businesses to use advanced technological means and to record the information required to be recorded according to Food Safety Law and these Regulations.

Article 28. Catering service providers shall establish and implement raw material procurement control measures and ensure the food and raw materials procured are in conformity with food safety standards.

During food processing, catering service personnel shall inspect the raw materials or food to be processed and shall not process or use them if they are found putrid or otherwise abnormal by sensory judgment.

Article 29. Catering service enterprises shall regularly maintain food processing, storage, display facilities and equipment and shall clean and calibrate cold storage and freezing facilities on a regular basis. Tableware and drinking ware shall be cleaned and sterilized as required and shall, after being sterilized, be kept ready for use in special clean cabinets. Tableware or drinking ware, if not sterilized, shall not be used.

Article 30. For food recalled under Article 53 of Food Safety Law, its producer shall have them harmlessly treated or destructed so as to prevent them from entering into market once again. Provided that the safety of the recalled food can be guaranteed with such remedial measures like making change in label, identification, and instruction manual, its producer may sell the food after taking such remedial measures.

AQSIQ, SAIC, and the food and drug administrative department at or above county level shall record in food producers' food safety and credit archive such information as recalling unqualified food or desisting from engaging in food that has been found unacceptable to food safety standards.

Chapter IV. Food Inspection

Article 31. Enterprises applying for re-inspection pursuant to Article 60 of Food Safety Law shall furnish required documents.

A catalogue of food inspection organizations trusted with re-inspection shall be announced jointly by CNCA, MOH, and MOA.

Article 32. Where a food producer is not in agreement with the sampling inspection conclusion as made under Article 60 of Food Safety Law and applies for a re-inspection, the re-inspection expense will be borne by the sampling inspection organization should the re-inspection find the food acceptable, otherwise the food producer shall bear the re-inspection expense.

Article 33. A food inspection organization performing food inspection at the request of a food producer or a food business operator shall immediately report to the health administrative department of the local county or district people's government having a

jurisdiction over the producer upon finding the furnished sample:

- (1) is contaminated by poisonous or harmful substance;
- (2) contains unidentified substances or non-food ingredients; or
- (3) is grossly not in compliance with food safety standards in such a way that food safety accidents may result.

Upon receiving the report, the health administrative department shall notify its local food safety supervision department without delay.

Chapter V. Food Import and Export

Article 34. When importing food from a country where no national food safety standard is in place or when importing a new food additive or a new variety of food-related product for the first time, the import agent shall submit the license as acquired under Article 63 of Food Safety Law when applying to AQSIQ for inspection.

After MOH has made a decision in favor of product import under Article 63 of Food Safety Law, AQSIQ shall conduct inspection according to the stipulations of MOH.

Article 35. Overseas food production enterprises that register pursuant to Article 65 of Food Safety Law for exporting food to the People's Republic of China shall have a registration validity of 4 years. During registration validity should the registered overseas food production enterprise be found having provided falsified files or the food imported from the enterprise has resulted in a major food safety accident, AQSIQ shall revoke the registration and have this decision publicized.

Article 36. Imported food additives shall be accompanied with a label and instructions in Chinese language. The label and instructions shall be in conformity with Food Safety Law and other relevant laws and administrative regulations of the People's Republic of China, as well as the requirements of national food safety standard and shall specify the place of origin of the additive and the name, address, and means of contact of its agent in the People's Republic China. Food additives without Chinese label or Chinese instructions or whose label or instructions are not in compliance with the provisions of this Article are not allowed to be imported.

Article 37. The regulations for the inspection of imported food by AQSIQ under Article 62 of Food Safety Law, as well as that for the supervision and sampling inspection of imported food by the same institution under Article 68 of Food Safety Law, shall be developed by AQSIQ.

Article 38. AQSIQ shall establish an information collecting network and shall collect, summarize and publicized the following information according to Article 69 of Food Safety Law:

- (1) Information on unsafe food as identified by AQSIQ during inspection and quarantine process;
- (2) Information reported by trade societies or consumers on imported food safety;

(3) Food safety information and risk warnings publicized by international organizations or overseas governmental institutions, as well as information reported by overseas trade societies or consumers on food safety; and

(4) Other information on food safety.

The department, thus acquainted with the information, shall take appropriate actions and measures when necessary. The food safety supervision and administration department shall notify AQSIQ of the acquired information on imported food safety.

Chapter VI. Handling of Food Safety Accidents

Article 39. The institution in which a food safety accident has occurred shall immediately seal off the food as well as its raw materials, tools, equipment and site that have or probably have caused this accident and shall, within 2 hours, report to the health administrative department of the local county or district people's government and shall take control measures as may be required by MOH.

Article 40. MOH, jointly with the food safety supervision and administration department and following the principle of science, shall investigate the food safety accident and timely and accurately find out the nature and cause of the accident and shall locate the responsibility for the accident and come up with rectification measures. The regulations for food safety accident handling shall be prepared by MOH.

Article 41. During the investigation into the food safety accident, MOH and the competent food safety supervision and administration department have the right to interview the institutions or individuals concerned for information related to the accident and may request that they provide relevant files and samples.

The institutions or individuals concerned shall cooperate with MOH and competent food safety supervision and administration department in their investigation of the accident and shall provide relevant files and samples as demanded.

Article 42. No institution or individual shall obstruct or interfere with the investigation in a food safety accident.

Chapter VII. Supervision and Administration

Article 43. The annual food safety supervision and administration plan prepared by a local people's government at or above county level under Article 76 of Food Safety Law shall cover food sampling inspection.

MOA, AQSIQ, SAIC, and the SFDA at or above county level shall conduct sampling inspection in accordance with the annual food safety supervision and administration plan. Expenses such as sample cost and inspection cost shall be covered by the budget outlay of its local government.

Article 44. When performing food safety supervision and administration and for the purpose of preliminary screening, the local quarantine officials, SAIC, and SFDA may employ a quick inspection method validated by the national level AQSIQ, SAIC, and SFDA. When the preliminary screening indicates that the food may not in conformity with food safety standard, the competent food safety supervision and administration department shall, pursuant to Article 60 of Food Safety Law, send the samples for inspection. However, preliminary screening results shall not be used as reference for law enforcement.

Article 45. Routine food safety supervision and administration information, as provided for in Article 82 of Food Safety Law, includes:

- (1) Work plan and arrangement for food safety supervision and administration;
- (2) Administrative license issued as per the Food Safety Law;
- (3) Supervision and inspection results of food producers and food business operators and food inspection results;
- (4) Catalogue of foods and food additives under key supervision and administration;
- (5) Catalogue of foods, food additives and food-related products for which an order has been given to cease producing or trading;
- (6) Illegal activities of food producers and business operators that have been investigated and punished;
- (7) Findings of targeted inspection and results of rectification and improvement; and
- (8) Other routine food safety supervision and administration information.

Should any information mentioned above involve two or more food safety supervision and administration departments, the information shall be publicized jointly by the competent departments.

Article 46 When publicizing information pursuant to Article 82 of Food Safety Law, the food safety supervision and administration department shall explain and describe any possible hazards associated with the food concerned.

Article 47 Each institution or individual is entitled to complain about and report illegal food production and business actions and report any identified unsafe food to MOH, MOA, AQSIQ, SAIC, or SFDA.

MOH, MOA, AQSIQ, SAIC, and SFDA shall publicize their email address or complaint and reporting phone number. Complaints and reports received shall be noted down completely and be filed.

Chapter VIII. Legal Liability

Article 48. Any food producer or business operator found in contravention of Article 19 of these Regulations shall be ordered to make rectification and be issued a warning punishment by the competent department; if serious consequences have been caused, punishment will be administered pursuant to Article 84 of Food Safety Law.

A catering service provider found in contravention of Article 28 of these Regulations shall be punished in accordance with Article 86 of Food Safety Law.

A food production enterprise found in contravention of Articles 22 through 25 of these Regulations, a food business enterprise engaging in food wholesale found in contravention of Article 26 of these Regulations, or a catering service enterprise found in contravention of Article 29 of these Regulations shall be punished in accordance with Article 87 of Food Safety Law.

Anyone found in contravention of Article 36 of these Regulations shall be punished in accordance with Article 89 of Food Safety Law.

Article 49. A medical institution found in contravention of Article 8 of these Regulations shall be ordered to make rectification and be issued a warning punishment by MOH.

Article 50. A food inspection organization found in contravention of Article 33 of these Regulations shall be ordered to make rectification and be issued a warning punishment by the competent department or organization that has qualified it; where serious consequences have been caused, its inspection qualification shall be revoked.

Article 51. Anyone found in contravention of Article 39 of these Regulations shall be punished in accordance with Article 88 of Food Safety Law.

Article 52. MOH, MOA, AQSIQ, SAIC, SFDA or other competent administrative department at or above county level shall be punished in accordance with Article 95 of Food Safety Law if they fail to perform food safety supervision and administration and information notification duties as required by these Regulations.

Article 53. Anyone who publicizes food safety information not in accordance with Food Safety Law and these Regulations and has, as a result, incurred losses to food producers or consumers shall assume indemnification liabilities.

Article 54. Anyone who falsifies or publicizes falsified facts to damage the commercial credit and food reputation of a food producer or business operator and has, as a result, incurred losses to the latter shall bear the indemnification liabilities; where a crime has been committed, the person guilty shall be subject to criminal liabilities.

Article IX. Supplementary Articles

Article 55. The following words and expressions of these Regulations shall have the meaning hereby assigned to them:

Food safety risk assessment refers to a scientific assessment performed in order to identify the possible adverse impact upon human health by biological, chemical and physical hazards of food; it includes hazard identification, hazard characteristic description, exposure assessment, and risk characteristic description, etc.

Catering service refers to service activities by which the food and food consumption premises and facilities are provided to consumers through instant preparation and processing, commercial sale and service labor.

Article 56. Farm food product quality safety risk monitoring and risk assessment shall be conducted by MOA in accordance with “Law of the People’s Republic of China on Agricultural Product Quality and Safety”.

The supervision and administration of catering service at borders and ports of the People’s Republic of China shall be conducted by the entry-exit inspection and quarantine organization in accordance with Food Safety Law and these Regulations.

Article 57. These Regulations are enforceable starting from June 01, 2009.